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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,441	10/02/2003	Anne-Marie Stomp	5051-337DVCT3	9042

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EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,441	STOMP ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10202005/4112005/*~~10222005/4042205/12312005~~ 10072007
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The status of the U.S. applications recited on page 1, line 6 needs to be updated.

Claim Objections

2. Claims 5, 6, 26 and 27 are objected to because of the following informalities:

In claims 5, 6, 26 and 27: all the recitations, "a species of ", should be deleted since the claims already refer to particular species.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stably transformed duckweed plants, plant cells and tissues produced by Agrobacterium-mediated transformation, does not reasonably

provide enablement for stably transformed duckweed plants, plant cells and tissues produced by other methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claims are broadly drawn to any stably transformed duckweed plant, plant cell or tissue comprising any heterologous nucleotide sequence of interest, or any chimeric nucleotide sequence of interest, incorporated in its genome.

The specification indicates that Lemna gibba fronds were subjected to particle bombardment with DNA comprising the GUS coding sequence (page 46, line 21 to page 47, line 12). The specification also indicates that Lemna, Spirodela, Wolfia, Wolfiela fronds, and Type I and II calli were transformed via Agrobacterium-mediated transformation, and that transformed Wolfia fronds were regenerated into plants (page 47, line 15 t page 90, line 10). Lemna Type I callus was also transformed via Agrobacterium-mediated transformation with constructs carrying the human β-hemoblobin or a P450 oxidase coding sequence (page90, line13 to page 91, line 26). The specification on pages 56-58 teaches the bombardment of Lemna gibba fronds and callus with microparticles coated with DNA comprising the GUS marker gene and an antibioltic resistance gene. Page 47, lines 8-12, indicates that GUS expressing cells were observed in the bombarded fronds. Page 48, lines 18-20, indicates that the selection of bombarded callus resistance to the selectable agent is continued for several weeks and that regeneration of transgenic fronds and plants is carried out as described in Example 42.

However, Example 42 describes regeneration from tissue transformed via Agrobacterium-mediated transformation. It appears that the bombarded duckweed fronds and callus were transiently transformed as there is no indication in the specification that stably transformed cells, tissue, or plants were recovered when transformed by microparticle bombardment. That bombarded frond tissue displayed GUS activity is not an indication that the cells of the frond tissue were stably transformed. Confirmation of stable transformation requires several tests, including a tight correlation between physical (e.g. a Southern blot) and phenotypic data (e.g. an enzyme activity assay), a complete Southern analysis, data that discriminates between false positives and correct transformants, and molecular and genetic analysis of offspring, for example (Potrykus, *Annu. Rev. Plant Physiol. Plant Mol. Biol.* 1991. 42:207-208). McCabe et al. (1993, *Plant Cell Tis. Org. Cult.* Vol. 33 page 231) stress that optimization or maximization of transient activity does not necessarily result in optimal or any stable transformation, and believe that studies indicating transiently expressing cells is meaningless and irrelevant to the final outcome particularly when the objective is recovery of transgenic plants. It is therefore unpredictable that the method taught in the specification can be used to produce stably transformed duckweed cells and plants. Given that the methods used for transient transformation is not predictive of steps needed for stable transformation, and in the absence of further guidance, undue experimentation would be required by one skilled in the art to produce stably transformed duckweed cells and plants using the methods taught in the specification. Given the teaching of McCabe et al., it is especially important that the specification

teach confirmation of stable transformation, as a transient gene expression assay system comprising microparticle bombardment of Lemna fronds has been known in the art for several years (Tobin et al., 1991, *NATO ASI Series*. 50:167-179, see pages 172-174). It is suggested that a declaration be submitted by the inventors showing data that confirm the recovery of stably transformed duckweed cells and plants using the microparticle bombardment methods taught in the specification.

Furthermore, the specification also does not teach any stably transformed duckweed plants, cells or tissues by any other methods since the transformation protocols discussed in the specification do not provide any information concerning other transformation methods. In the absence of further guidance, undue experimentation would be required by a person skilled in the art to stably transform duckweed plants, cells or tissues by methods other than Agrobacterium-mediated transformation. See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

While a specification only needs to enable one method of making a claimed product, it is noted that the claimed products produced via Agrobacteria-mediated transformation would differ structurally from those produced by other methods because of the presence of T-DNA.

Given the breadth of the claims encompassing all stably transformed duckweed plants, cells and tissues, comprising any heterologous or chimeric nucleotide sequence of interest, produced by any method, unpredictability of the art and lack of further

guidance, undue experimentation would be required by a person skilled in the art to make and use the claimed invention in its full scope.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-20, 22-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-7, 20-29, 39 of U.S. Patent No. 6,040,498,

More specifically, claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 22, 23, 24, 24, 24, 25, 26, 27, 28 and 29 of U.S. Patent No. 6,040,498, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-11 are generic to all that are recited in claims 20-29 of U.S. Patent

No. 6,040,498, respectively. In other words, instant claims 1-11 are anticipated by claims 20- 29 of U.S. Patent No. 6,040,498, respectively. The instant claims are drawn to any stably transformed duckweed plants whereas the corresponding claims of U.S. Patent No. 6,040,498 are drawn to stably transformed duckweed plants via Agrobacterium-mediated transformation.

Although claim 3 of U.S. Patent No. 6,040,498 is drawn to a method whereas instant claims 13, 18 and 19 are drawn to transgenic tissue, tissue/culture or cells, it is obvious that the method of claim 3 of U.S. Patent No. 6,040,498 produces the transgenic tissue, tissue/culture or cells which anticipate instant claims 13- 19.

Although claim 39 of U.S. Patent No. 6,040,498 is drawn to a method to produce the protein whereas instant claims 12 and 33 are drawn to transgenic plant, it is obvious that the method of claim 39 of U.S. Patent No. 6,040,498 produces the transgenic plants that anticipate instant claims 12 and 33.

5. Claim 21 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 44 of U.S. Patent No. 6,040,498 in view of Okubara et al. (1991, *Plant Physiol.* 96:1237-1245).

Claim 21 reads on stably transformed duckweed plant expressing a chimeric nucleotide sequence comprising a duckweed coding sequence oeprably linked to a transcriptional initiation region that is heterologous to said coding sequence.

Claim 44 of U.S. Patent No. 6,040,498 teaches a method of stably transforming duckweed tissue with a vector containing CaMV 35S promoter.

Claim 44 of U.S. Patent No. 6,040,498 does not teach the coding sequence from duckweed.

Okubara et al. teach that three genes negatively regulated by phytochrome action were isolated from Lemna gibba which is a duckweed plant.

It would have been obvious for a person with ordinary skill in the art to using the vector of Claim 44 of U.S. Patent No. 6,040,498 to express three genes of Okubara et al. in *Lemna gibba*. One would have motivated to do so given the teaching of Okubara et al. that those genes are negatively regulated by phytochrome action in Lemna gibba (abstract) and therefore it is a routine approach in the art to study possible roles of those genes involved in phytochrome action by overexpression.

6. Claims 1-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 8, 12, 52, 58, 61, 78-80 of copending Application No. 10/273,974.

More specifically, claims 1-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 8, 12, 52, 58, 61, 78-80 of copending Application No. 10/273,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transgenic duckweed plants, tissues, tissue culture or cells are obtained by the methods of claims 1, 4-6, 8, 12, 52, 58, 61, 78-80 of copending Application No. 10/273,974. The methods of 10/273,974 recite the limitations regarding the introduced nucleotide sequences that are recite in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted, however, that 10/273,974 has been allowed. This provisional rejection will become a rejection over the patent upon its issuance.

7. Claims 1-10, 12-31, 33-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 22-25 of U.S. Patent No. 6,815,184. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claims 1, 22-25 of U.S. Patent No. 6,815,184 involved in transgenic duckweed plant culture expressing secreted version of α-interferon. Although the copy number, selection marker, T-DNA board sequence, or particular tissue types are not taught, there are inherently present in Agrobacterial transformed duckweed plant. Therefore, the claims 1 and 22-25 of U.S. Patent No. 6,815,184 teach all the limitation in Claims 1-10, 12-31, 33-40.

8. Claims 11 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. (1995,Transfus Clin Biol. 2:441-447).

The method of claims 1 of U.S. Patent No. 6,815,184 involved in transgenic duckweed plant culture expressing secreted version of α-interferon.

Claim 1 of U.S. Patent No. 6,815,184 does not teach hemoglobin, collagen, P450 oxidase or monoclonal antibody.

Dieryck et al. teach use of a transgenic plant to produce recombinant hemoglobin (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the method of claim 1 of U.S. Patent No. 6,815,184 to express hemoglobin instead of α - interferon, resulting in the instant invention. One would have been motivated to do so given the teaching of Deiryck et al. that using transgenic plant to produce hemoglobin allows low cost with minimal risks of pathogen contamination (abstract).

7. Claims 1-10, 12-31, 33-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 22-25 of copending Application No. 10/873,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claims 1, 22-25 of Application No. 10/873,846 involved in transgenic duckweed plant culture expressing secreted version of α-interferon. Although the copy number, selection marker, T-DNA board sequence, or particular tissue types are not taught, there are inherently present in Agrobacterial transformed duckweed plant. Therefore, the claims 1 and 22-25 of U.S. Patent No. 6,815,184 teach all the limitation in Claims 1-10, 12-31, 33-40.

8. Claims 11 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,815,184 in view of Dieryck et al. (1995,Transfus Clin Biol. 2:441-447).

The method of claims 1 of U.S. Patent No. 6,815,184 involved in transgenic duckweed plant culture expressing secreted version of α-interferon.

Claim 1 of U.S. Patent No. 6,815,184 does not teach hemoglobin, collagen, P450 oxidase or monoclonal antibody.

Dieryck et al. teach that use transgenic plant to produce recombinant hemoglobin (abstract).

It would have been obvious for a person with ordinary skill in the art to modify the method of claim 1 of U.S. Patent No. 6,815,184 to express hemoglobin instead of α - interferon, resulting the instant invention. One would have been motivated to do so given the teaching of Deiryck et al. that using transgenic plant to produce hemoglobin allows low cost with minimal risks of pathogen contamination (abstract).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

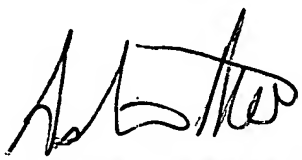
Claims 1-40 are rejected. The instant claims, however, are deemed free of prior art due to the fact that the prior art fails to teach or suggest the duckweed transformation.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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